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Re-evaluation Note

REV2013-04

Special Review of Compound 1080

(publié aussi en français)

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Overview

Proposed Special Review Decision for Compound 1080

After a special review of the predicide Compound 1080 (sodium monofluoroacetate), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing continued registration of Compound 1080 products for the sale and use in Canada.

An evaluation of available scientific information found that Compound 1080 does not pose unacceptable risks to the environment provided new risk-reduction measures are included on the labels of all products as a condition of continued registration. No additional data are required.

This proposal affects all end-use products containing Compound 1080 formulated as tablets registered in Canada. Once the final special review decision is made, registrants will be instructed on how to address any new requirements.

The regulatory approach regarding the special review of Compound 1080 was published in Re-evaluation Note, Special Review Initiation of Compound 1080 on 23 December 2011.¹ The focus of the special review was to re-examine the potential risks to non-target organisms when tablets containing Compound 1080 are used in baits and whether current mitigation measures (for example, labelling and application instructions) continue to be acceptable.

This proposed special review decision is a consultation document² that summarizes the science evaluation for Compound 1080 and presents the reasons for the proposed special review decision.

This consultation document is presented in two parts. This Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed information on the environmental risk assessment of Compound 1080. A full copy of the Science Evaluation is available upon request through Publications.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

¹ Special Review Initiation of Compound 1080, REV2011-06, 23 December 2011.

² "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Special Review Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.³ The Act also requires that products have value⁴ when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as science-policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and science-policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pesticide Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a special review decision on Compound 1080, the PMRA will consider all comments received from the public in response to this consultation document.⁵ The PMRA will then publish a special review decision document⁶ on compound 1080, which will include the decision, the reasons for it, a summary of comments received on the proposed special review decision and the PMRA's response to these comments.

For more details on the information presented in this overview, please refer to the Science Evaluation.

³ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

⁵ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁶ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What is Compound 1080?

Compound 1080 is an animal toxicant used to control wolves and coyotes in the provinces of Alberta and Saskatchewan only. Products containing this active ingredient are registered as restricted-class products. Two formulations exist as either tablets or livestock collars with liquid containing Compound 1080. Compound 1080 can be applied as meat baits containing tablets or as a collar device on livestock. Application ranges from 1–12 tablets (5 mg/tablet of Compound 1080) in meat baits relative to the size of the bait (larger baits require more tablets) or one 60 mL collar device (10 mg/mL of Compound 1080) per livestock.

Environmental Considerations

What Happens When Compound 1080 is Introduced Into the Environment?

Compound 1080 poses a risk to birds and mammals; therefore, additional risk-reduction measures need to be observed.

Compound 1080 can enter the environment when meat baits containing the tablet formulation of this chemical are deployed to attract and kill nuisance wolves and coyotes. Use of this product is severely restricted as it is highly toxic to birds and mammals. Mammals are the most sensitive species particularly canids (for example, dogs). Non-target carnivores may also be exposed to Compound 1080 if they are attracted to bait stations and ingest any tablets. In order to further mitigate risk to non-target birds and mammals, additional label restrictions are proposed on product labels relating to how the product may be used. In recognition of species at risk which are known to exist in areas where Compound 1080 may be applied, an additional label restriction to prohibit use of Compound 1080 in these designated areas is also proposed.

Compound 1080 is highly water soluble and not bioaccumulative, hence it is not expected to be persistent and does not meet any of the Track 1 criteria under the Toxic Substances Management Policy.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The following additional key risk-reduction measures are being proposed to address potential environmental risks identified in this assessment. These measures, in addition to those already present on existing Compound 1080 product labels, are intended to minimize risks to the environment.

Additional Key Risk-Reduction Measures

Environment

- To minimize risk to non-target species, additional statements are required on product labels to further reduce the potential for exposure. These statements include use directions relating to:
 - Burying of multi-dose baits for the control of coyotes;
 - Placement of tablets deep into cuts made in carcasses to reduce exposure to scavenging birds;
 - Destruction and disposal of poisoned carcasses;
 - Disposal of vials or unused compound 1080 product; and
 - Addition of a statement prohibiting use of Compound 1080 in designated areas where species at risk exist.

What Additional Information is Being Requested?

The risk to the environment has been found to be acceptable when all risk-reduction measures are followed and implemented. No additional information is being requested from registrants as a result of this special review.

Next Steps

Before making a special review decision on Compound 1080, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Other Information

The test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

1.0 Introduction

Compound 1080 is an animal toxicant used to control wolves and coyotes in the provinces of Alberta and Saskatchewan only. Products containing this active ingredient are registered as restricted-class products. Following the special review announcement for Compound 1080, registrants of end-use products (Alberta Agriculture and Rural Development; Saskatchewan Ministry of Environment) indicated their intention to provide continued support for all uses included on the labels of registered products.

The PMRA re-evaluated Compound 1080 in April 2005⁷ based on the 1995 United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED),⁸ which focused only on the use of Compound 1080 in livestock collars. Considering the information and context of the 2005 PMRA re-evaluation, the PMRA made a decision to conduct a special review of Compound 1080 with a focus on the tablet formulation only as the use of collars was adequately addressed in the PMRA re-evaluation. Therefore, this special review will consider information on the current use and application of Compound 1080 tablets in Canada and other countries, the environmental fate and effects of Compound 1080, the environmental risk from the use of Compound 1080, and the current label mitigation measures for registered products.

2.0 The Active Ingredient and Its Properties

2.1 Identity of the Active Ingredient

Common name	Sodium monofluoroacetate or Compound 1080
Function	Predacide
Chemical family	Acetate
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Sodium fluoroacetate
2. Chemical Abstracts Service (CAS)	Fluoroacetic acid, sodium salt
CAS Registry Number	62-74-8
Molecular formula	C ₂ H ₂ FNaO ₂

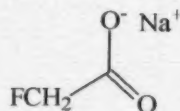
⁷ Re-evaluation Decision Document, Sodium Monofluoroacetate, RRD2005-05, 19 April 2005.

⁸ United States Environmental Protection Agency Reregistration Eligibility Decision, Sodium Fluoroacetate (EPA 738-R-95-025), September 1995.

Molecular weight

100.02

Structural formula



Identity of relevant impurities of human health or environmental concern

Compound 1080 is a large monovalent anion with a simple carboxylic acid structure and one fluorine atom. Based on its structure, Compound 1080 may be expected to be easily degraded in the environment (Wong et al., 1992; Goh et al., 2005).

Based on the chemical structure of the active ingredient, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Active Substance

Property	Result
Vapour pressure at 25°C	Not applicable for ionic inorganics.
Ultraviolet (UV)/visible spectrum	Not expected to absorb at $\lambda > 250$ nm.
Solubility in water at 20°C	Soluble.
n-Octanol/water partition coefficient (log Kow)	Not applicable to inorganic salt.
Dissociation constant (pKa)	Completely dissociates in water.

2.3 Description of Registered Uses

Appendix I lists all Compound 1080 products that are registered under the authority of the *Pest Control Products Act*. All uses were supported by the registrant at the time of the special review initiation and were therefore considered in the environmental risk assessment of Compound 1080.

3.0 Compound 1080 Use

Mode of Action

When Compound 1080 is ingested, it is absorbed and binds to coenzyme A to form fluoroacetyl-CoA which can substitute to acetyl-CoA in the citric acid (Krebs) cycle and reacts with citrate synthetase to produce fluorocitrate. Fluorocitrate is a potent inhibitor of the enzyme aconitase.

When this cycle is blocked, the cell ceases to function through lack of energy and citrate accumulates in the tissue and plasma. This accumulation may cause convulsions and death from cardiac failure or respiratory arrest. It is toxic to all warm blooded animals, but the degree of toxicity varies between species.

The time taken for fluorocitrate to reach lethal levels and for symptoms to be exhibited is estimated to be between 30 and 150 minutes, depending on the species and dose.

Additional Information Considered

Compound 1080 is currently registered in several countries, including Canada, the United States, Australia, Mexico, Japan, Korea, and Israel. Available information from the United States and Australia that was relevant to this special review was considered.

Current information on the deployment of this predicide to control wolves and coyotes was received from the Alberta Department of Agriculture and Rural Development (AARD) and the Saskatchewan Ministry of the Environment (SMoE). These products and uses are discussed in the following section.

3.1 Collars

This product consists of a collar with an attached vial containing 60 mL of Compound 1080 (10 mg/mL) solution. The collar is affixed around the neck of the sheep or goats (juveniles). The chemical is released when the vial is punctured during a predator attack.

Based on provincial use information, Compound 1080 neck collars are only used occasionally and there may be several years between periods of use. This product is most effective in situations where a specific pattern of coyote predation on lambs weighing 50 pounds (23 kg) or more has been established; however, its use is very labour intensive and time consuming. Exposure to non-target organisms, through scavenging, may occur within the few hours between the moments after a coyote attacks and kills a collared lamb until the producer removes the carcass. The environmental hazards posed by neck collars were adequately addressed in the 2005 PMRA re-evaluation and therefore will not be characterized further in this special review.

3.2 Tablets

3.2.1 Usage in Alberta

Products consist of a solid tablet containing 5 mg of Compound 1080 that are applied by inserting them in meat baits composed of animal parts (for example, chicken heads, viscera, meat) or in an entire carcass (for example, carcass of a goat or sheep killed by the targeted predator). Baits are placed in areas where there has been evidence of sheep and goat predations. Coyotes and wolves are attracted to these baits and upon consumption of the meat laced with Compound 1080; they subsequently die due to poisoning.

Four types of bait stations are described on the registered product label: single and multi-dose baits for coyotes and small or large baits for wolves.

Coyotes

Single dose bait: These bait stations consist of a meat bait (for example, chicken heads) of approximately 100 g into which one tablet is inserted and then covered with 5–10 cm of either snow, soil, vegetation or other material to prevent exposure to birds. Up to three baits are placed at a time. The carcass is located at a site where coyote predation has been confirmed to have occurred within the previous 30 days.

Multi-dose bait: These bait stations consist of an animal carcass (for example, goat or sheep) in which up to six tablets are placed at a site where coyote predation has been confirmed within the previous 30 days.

Wolves

Small baits: These bait stations consist of a meat bait (for example, chicken heads, viscera, meat) of approximately 100 g in which three tablets are placed and then covered with 30 cm of snow or 15 cm of loose soil. The bait stations are situated along trails leading to an untreated carcass or in a circle around an untreated carcass.

Large baits: These bait stations consist of an animal carcass (for example, goat or sheep) that is securely anchored and in which up to twelve tablets are concealed. The carcass is then covered with 30 cm of snow or 15 cm of loose soil.

All the above mentioned bait stations must be monitored every 7 days by authorized personnel and removed after 15 days.

Information provided by the AARD indicated that approximately 1500 individual tablets are typically deployed on a yearly basis. On average, approximately six tablets are set out at each site of a confirmed coyote predation complaint. The tablets are inserted into the meat of the carcass of a goat or sheep that has been killed by a coyote or in the throat of a chicken head. Tablets inserted into the carcass are placed deep in horizontal cuts reducing the likelihood of birds ingesting the tablets as scavenging birds feed by pecking and tearing of small pieces of tissue. Tablets placed in a chicken head are not accessible to birds or small scavengers as they are unable to crush the skull of a chicken head.

The AARD relies heavily on the use of Compound 1080 to successfully operate its Coyote Management Control Program. Approximately 300 producers per year rely on Compound 1080 tablets to relieve their livestock predation problems. The AARD personnel and trained agricultural producers who are authorized to use poison under this program must be trained and able to demonstrate responsible use in strict accordance with the regulations under the *Alberta Agricultural Pest Act* and the federal *Pest Control Products Act*. Every two years, the AARD facilitates a provincial training course specific to coyote control methods. The proper and safe

use of coyote control toxicants is a significant part of the AARD's training program. Regional training courses are also conducted on a yearly basis to train new staff.

The AARD confirmed that poison use is only considered as a last resort to control coyote predation when other methods have proved unsuccessful. Livestock management practices are promoted as the best solution for long-term coyote control. For example, guard dogs are strongly recommended as an option to sheep and goat producers. Habitual coyote predation of sheep and goats require the implementation of guard dogs as a first step before the use of toxicants are considered.

3.2.2 Usage in Saskatchewan

The use description and application of Compound 1080 in the province of Saskatchewan are identical to that outlined above for Alberta and therefore are not repeated here.

The SMoE provided information pertaining to their provincial policies and guidelines on the use of Compound 1080 for predator control. This information included authorization procedures, eligibility criteria, limitations and restrictions for the use of Compound 1080 products; however, information was absent regarding the extent of use of Compound 1080. Information detailing the SMoE predacide training course, provided to provincial personnel (applicators) and approved agents, was also provided and included use, storage and handling information for Compound 1080 products.

The SMoE may not permit the use of Compound 1080 if it is determined that insufficient precautions have been taken to prevent predator problems. In order to be eligible to apply Compound 1080 tablets, a livestock producer must be able to demonstrate that all other available methods to control the problem have been employed. This includes attempts to use traditional methods of predator control such as trapping, snaring, shooting and den-hunting as well as proper disposal of dead livestock, use of guardian animals, night-penning and/or use of predator-proof fencing to protect lambing pastures or corral areas. If the use of Compound 1080 is authorized, only SMoE trained applicators or their approved agents may apply Compound 1080 and set baits.

4.0 Impact on the Environment

4.1 Exposure of Non-Target Species

4.1.1 Exposure of Non-Target Birds and Mammals

Tablets containing Compound 1080 are currently registered for use only in the provinces of Alberta and Saskatchewan. Considering this, and the feeding habits of non-target animals that may frequent these areas of use, the non-target animals likely to be exposed to baits containing Compound 1080 tablets are scavenging birds and mammals. The following discussion characterizes how non-target scavenging birds and mammals may have the potential to be exposed to Compound 1080 tablets.

Non-target birds and mammals may be exposed to Compound 1080 through two potential routes of ingestion. Exposure may occur by primary poisoning through direct ingestion of tablets in baits or by secondary poisoning through the consumption of the carcass, stomach contents, or vomitus of poisoned animals. Secondary poisoning was previously assessed in the 2005 PMRA re-evaluation and this route of exposure was deemed not a concern as non-target animals would have to consume large quantities in order to reach a lethal dose. The potential occurrence of secondary poisoning would be similar regardless of whether a poisoned animal was exposed to a collar or tablet formulation of Compound 1080. Therefore, secondary poisoning will not be discussed further in this special review and the focus will be on the potential for primary poisoning of non-target scavengers (birds and mammals) through direct ingestion of tablets in baits.

Non-target scavengers may be exposed to Compound 1080 through ingestion of tablets in meat baits that are deployed when a wolf or coyote attack pattern is confirmed and other means of control were unsuccessful (for example, use of guard dogs, hunting, corralling, etc.). A confirmed attack pattern implies that predators will repetitively return to the attack site. According to the registered product labels (refer to Section 3.0), small baits (100g of meat/viscera/chicken heads containing 3 tablets) and single-dose baits (100g of meat/viscera/chicken heads containing 1 tablet, up to 3 baits per station) for coyote control as well as large baits (carcass of sheep or goats killed by targeted predator containing up to 12 tablets) for wolf control are required to be covered in loose soil or snow. This would effectively reduce exposure of the bait to non-target scavengers by reducing visual cues and the emanation of decomposition gasses associated with meat baits (Bischoff-Mattson and Mattson, 2009) without inhibiting the potential to attract the targeted predators. However, statements requiring the covering of multi-dose baits to control coyotes (bait consists of 6 tablets and the carcass of a sheep or goat killed by the targeted predator) are absent from registered product labels. Olfactory cues are important for attracting many scavengers and the absence of these statements would increase the potential exposure of non-target scavengers to Compound 1080.

When small or single-dose baits are found by targeted animals (wolves or coyotes), they are likely to be consumed immediately upon discovery thus reducing the potential for exposure to non-target scavengers. Conversely, when large baits are discovered, large scavenging mammals (targeted or non-targeted) may potentially dig up these baits and leave them exposed and more readily available to other animals. In addition, sheep-sized carcasses used in large baits or multi-dose baits are not likely to be consumed entirely upon discovery, thus there is a potential for non-target scavengers to be exposed to Compound 1080.

As mentioned above, scavenging birds may be exposed to Compound 1080 tablets in exposed carcasses (large and multi-dose baits). According to application information from the AARD, tablets should be positioned in the carcasses in such a way to prevent birds from having direct access to them. Tablets inserted into the carcass are placed deep in horizontal cuts reducing the likelihood of birds ingesting the tablets since scavenging birds feed by pecking and tearing small pieces of tissue. As such, further discussion in this document will focus on product label wording to ensure that existing statements on all product labels reflect the above method to reduce access by scavenging birds.

4.1.2 Effects on Non-Target Species

Information on the toxicological endpoints of Compound 1080 for mammalian and avian species are presented to facilitate a discussion on the relative toxicity of Compound 1080 and its targeted use against coyotes and wolves. The endpoint values reported in this document were obtained from the 1995 United States Environmental Protection Agency Reregistration Eligibility Decision for sodium fluoroacetate (refer to Appendix II).

Mammals are highly sensitive to Compound 1080 and this substance is classified as highly to very highly toxic. Canids, such as dogs and coyotes, are among the most sensitive organisms. It can be reasonably assumed that Compound 1080 will also be highly toxic to canids other than those represented in these test results, such as foxes. The extensive use of Compound 1080 in Australia for the control of dingos, wild dogs, and foxes is a further indication of its effect on this group of organisms. Compound 1080 is also highly to very highly toxic to birds. However, birds are up to two orders of magnitude less sensitive to Compound 1080 than mammals.

4.2 Risk Characterization

To characterize the risk to non-target organisms, the feeding behaviour of the non-target scavengers that have the potential to be exposed to Compound 1080 tablets were compared to the different bait types and how they are deployed. Current label mitigation measures were assessed and where a concern to non-target scavenging birds and/or mammals is identified, additional mitigation measures are proposed to be implemented on Compound 1080 tablet labels.

Given the limited geographic area where Compound 1080 can be used as well as the narrow use pattern targeting vertebrate predators/scavengers, the potential for exposure of local species at risk is also discussed.

4.2.1 Mammals

In Canada, the primary method for delivering Compound 1080 is in meat-based baits, which are buried under loose soil or snow. Covering the baits in soil or snow acts to mask the odour emanated by the decomposition of the meat bait making them less attractive to scavengers (Bischoff-Mattson and Mattson, 2009). Additionally, decomposition will significantly decrease or cease completely in the cold of winter thus further reducing their attractiveness to scavengers. Considering the limited and restricted use of these baits and the duration of exposure (baits are monitored every seven days and removed after 15 days), scavenging mammals are not expected to be significantly exposed to small baits and single-dose baits therefore the use of these baits are not a concern for these populations. There is currently no label requirement to cover multi-dose baits with soil or snow in order to target coyotes which increases the probability of non-target scavengers detecting the bait in comparison to covered baits. As such, the risk to non-target scavenging mammals exposed to uncovered multi-dose baits is a concern. A label statement requiring that multi-dose baits for coyote control must be covered with loose soil or snow is warranted to reduce potential for exposure of non-target scavenging mammals.

Exposure of non-target mammals is also more likely to occur from the use of large or multi-dose baits which may not be consumed entirely by the targeted predator. Although large baits are required to be covered by loose soil or snow, they may become uncovered and left visibly exposed thereby increasing the likelihood of detection by other non-target mammals. This potential for exposure is currently mitigated by the existing label requirement to visit the treatment site every seven days thereby limiting the amount of time the carcass may be left exposed.

Overall Risk Conclusions for Mammals

Although there is a potential for non-target scavenging mammals to be exposed to Compound 1080 tablets through the consumption of exposed baits (i.e. buried baits that are uncovered and not consumed entirely by targeted predators), the very limited and restricted use of tablets makes it unlikely that the potential effects would pose an unacceptable risk to most non-target scavenging mammal populations.

Mitigation measures are already outlined on product labels for the tablet formulation in order to reduce the potential for exposure of non-target mammals. Nonetheless, concerns were identified during this review for which additional mitigative statements are required to further strengthen existing protective measures on product labels.

4.2.2 Birds

Most scavenging birds forage using olfaction (Bruiton and Nuechterlein, 1985), among other cues, and are not known to dig for their food. Consequently, covering the baits in soil or snow should reduce the likelihood that a scavenging bird will locate a baited carcass by sight or smell. However, the product labels for Compound 1080 do not state that the multi-dose baits targeting coyotes are to be covered in soil or snow. Scavenging birds are more likely to be attracted to these uncovered baits because they are easier to locate by smell or by sight. As such, additional mitigative label statements are warranted to reduce the potential for exposure to Compound 1080 in multi-dose baits.

Although large baits are required to be covered by loose soil or snow, they may become uncovered and left visibly exposed thereby increasing the likelihood of detection and availability to scavenging birds such as turkey vultures or black-billed magpies. Due to the feeding behaviour of scavenging birds (pecking and tearing of small pieces of tissue), tablets should be placed in the carcass in such a way to further reduce the potential exposure of these birds, such as being placed in deep cuts into the meat tissue as described by the AARD (refer to Section 4.1.1). Despite the very limited and restricted use of tablets, a label statement to that effect is warranted on tablet product labels to further reduce the potential for exposure to tablets.

Overall Risk Conclusions for Birds

Although there is a potential for exposure to Compound 1080 directly through the consumption of tablets in baits, the risk to scavenging birds is low and should not cause adverse effects to bird populations. Nevertheless, label statements requiring the applicator to place tablets into carcasses in such a way as to further reduce the potential for exposure to birds is recommended.

4.3 Species at Risk

The successful recovery of a Species at Risk depends not only on reproductive success but also the survival of each individual. Due to the high toxicity of this chemical to mammals, only a relatively small amount of Compound 1080 would be necessary to kill a small carnivorous predator/scavenger. Although the toxicity of Compound 1080 to birds is less than that for mammals, it is possible that a bird could consume a lethal dose. Considering the small population size of most Species at Risk, exposure to poisoned baits is a concern and use must be avoided in areas where they are present.

5.0 Incident Reports

No incident reports in Canada were identified for Compound 1080.

Incident reports relating to use of Compound 1080 identified in the United States were considered in the 2005 PMRA re-evaluation.

6.0 Proposed Regulatory Decision

Health Canada's PMRA has completed the special review of Compound 1080 and has concluded that the use of this chemical is severely restricted with a targeted use pattern. For example:

- Only trained licensed people can handle and deploy Compound 1080;
- Tablets are supplied to the user by the provincial authority and are the property of the province at all times;
- Only a maximum of six tablets may be issued at one time;
- Use of tablets is permitted only as a last resort when other means of livestock protection are unsuccessful (for example, hunting and other non-lethal methods such as livestock guardians, trapping, etc.);
- Bait stations must be monitored every 7 days and removed after 15 days;
- Small baits using chicken heads are preferred due to ease of use and the lower potential exposure to non-target species.

Therefore, the use of tablet products containing Compound 1080 is not expected to seriously impact most scavenging mammalian and avian populations provided that the mitigation measures presented in this document are implemented.

6.1 Proposed Regulatory Actions

The risk assessment of the tablet uses of Compound 1080 identified a potential risk for exposure of non-target organisms. In order to mitigate this potential risk, additional mitigation measures to reduce the potential exposure of non-target birds and mammals are required. Revised labels will require the burying of multi-dose baits for the control of coyotes and the placing of tablets deep in cuts in carcasses to reduce exposure to birds. To reduce the potential exposure of local Species at Risk, revised labels will prohibit the use of baits in areas where populations of scavenging species at risk are known to be present. In addition, revisions are required to harmonize product labels between Alberta and Saskatchewan relating to disposal of poisoned carcasses and unused product. The proposed mitigation measures and additional label statements are presented in Appendix III.

6.2 Additional Data Requirements

No additional data is required.

List of Abbreviations

µg	micrograms
AARD	Alberta Department of Agriculture and Rural Development
ADI	acceptable daily intake
a.i.	active ingredient
bw	body weight
cm	centimeter
g	gram
ha	hectare
kg	kilogram
L	liter
LC50	lethal concentration 50%
LD50	lethal dose 50%
LOEL	lowest-observed-effect-level
Log K_{ow}	n -Octanol-Water partition coefficient
mL	milliliter
nm	nanometer
NOEL	no-observed-effect-level
mg	milligram
pKa	Dissociation constant
ppm	parts per million
SMoE	Saskatchewan Ministry of the Environment
TGAI	technical grade active ingredient
USEPA	United States of America Environmental Protection Agency
UV	Ultra violet

Appendix I Registered Compound 1080 Products as of 21 November 2011

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
18300	Restricted	Alberta Agriculture and Rural Development	Sodium Monofluoroacetate Predacide	Tablet	5 mg/tablet
24512	Restricted	Alberta Agriculture and Rural Development	Sodium Monofluoroacetate Restricted Toxic Collar Solution	Solution	10 mg/mL
25857	Restricted	Saskatchewan Ministry Of Environment	Sodium Monofluoroacetate (Compound 1080) Predacide Tablets	Tablet	5 mg/tablet
28865	Restricted	Saskatchewan Ministry Of Environment	Sodium Monofluoroacetate - Toxic Collar Solution	Solution	10 mg/mL

Note: Discontinued products and products with submissions for discontinuation have not been included.

Appendix II Mammalian and Avian Toxicological Endpoints of Compound 1080

Table 1 Mammalian toxicological endpoints as reported in the 1995 United States Environmental Protection Agency Reregistration Eligibility Decision of sodium monofluoroacetate (Compound 1080)

Species	Endpoint	Toxicity Classification ^a
Acute oral (LD₅₀; mg a.i./kg bw)		
Rats	0.1–0.22	Very highly toxic
Coyotes	0.12	Very highly toxic
Dogs	0.066	Very highly toxic
Mice	0.50	Very highly toxic
Rabbits	0.34	Very highly toxic
Cotton rat	0.1	Very highly toxic
Deer mouse	4.0	Very highly toxic
Raccoon	1.1	Very highly toxic
Opossum	41.6	Highly toxic
Skunk	1.0	Very highly toxic
Acute dermal (LD₅₀; mg a.i./kg bw)		
Rabbits	277.1–324.2	Moderately toxic
Subchronic (NOEL mg a.i./kg bw/day)		
Rats (13 weeks gavage)	0.05 (LOEL=0.20)	Very highly toxic
Rats (7-day drinking water)	0.19 (LOEL=0.07)	Very highly toxic

^a according to the United States Environmental Protection Agency toxicity classification

Table 2 Avian toxicological endpoints as reported in the 1995 United States Environmental Protection Agency Reregistration Eligibility Decision for sodium monofluoroacetate (Compound 1080)

Species	Endpoint	Toxicity Classification ^a
Acute oral (LD₅₀; mg a.i./kg bw)		
Mallard	9.1	Very highly toxic
Chukar	3.5	Very highly toxic
Ring-neck pheasant	6.4	Very highly toxic
Widgeon	3.0	Very highly toxic
Golden eagle	5.0	Very highly toxic
Black vulture	15.0	Highly toxic
Black-billed magpie	1.0– 2.3	Very highly toxic
Subacute (LC₅₀; mg a.i./kg feed)		
Mallard	486	Highly toxic
Bobwhite quail	231	Highly toxic

^a according to the United States Environmental Protection Agency toxicity classification

Appendix III Label Amendments for Products Containing Compound 1080

The following label amendments are required for registered end-use products formulated as tablets.

Registration Number 18300 – Alberta

In the section called **RESTRICTED USES, COYOTE**, under the **Multi Dose Bait** heading, the following sentence must be removed:

Place up to six tablets into a carcass at a coyote control site.

Replace with:

Place up to six tablets into a carcass at a coyote control site and then cover with 30 cm of snow or 15 cm of loose soil.

Under the **Use Limitations** section, the following statements must be added:

Tablets inserted into a carcass should be placed deep in a horizontal cut to prevent scavenging birds from accessing the tablet.

For use only to control offending animals in areas where proper herd management is practiced to discourage predation.

To prevent hazard of secondary poisoning, any baits removed from use or the carcasses of poisoned coyotes or wolves must be burned or buried to a depth of 60 cm (2 feet). Vials and unused product must be disposed of in accordance with provincial requirements.

Do not apply this product if species at risk (for example the swift fox) that may feed on Compound 1080 bait or on poisoned carcasses are present in your area. For information on species at risk in your area, contact the Fish and Wildlife Division of Alberta Sustainable Resource Development.

The following limitation should be **removed**:

The user of tablets must remove and destroy poison bait within 30 days of placement between April and October 31st and within 90 days of placement between November and March 31st.

Registration Number 25857 – Saskatchewan

In the section called **RESTRICTED USES, COYOTE**, under the **Multi Dose Bait** heading, the following sentence must be removed:

Place up to six tablets into a carcass at a coyote control site.

Replace with:

Place up to six tablets into a carcass at a coyote control site and then cover with 30 cm of snow or 15 cm of loose soil.

Under the **Limitations** section, the following statements must be added:

Tablets inserted into a carcass should be placed deep in a horizontal cut to prevent scavenging birds from accessing the tablet.

Do not apply this product if species at risk that may feed on Compound 1080 bait or on poisoned carcasses are present in your area. For information on species at risk in your area, contact the Saskatchewan Ministry of Environment Fish and Wildlife Branch.

The following limitation must be revised:

*To prevent hazard of secondary poisoning, any baits **removed from use** or the carcasses of poisoned coyotes or wolves must be burned or buried to a depth of 60 cm (2 feet). Vials and unused product must be disposed of in accordance with provincial requirements.*

References**A) Applicant Supplied Information****PMRA
Document
Number****Title**

- | | |
|---------|--|
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B) PMRA's Previous Evaluations

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C) Additional Information – Published**PMRA
Document
Number****Title**

- | | |
|---------|--|
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- 2223911 APVMA, 2008. Sodium Fluoroacetate: Final review report and regulatory decision.
- 2223914 US EPA, 2010. Problem Formulation for Ecological Risk Assessment of Sodium Fluoroacetate (1080).
- 2223915 US EPA, 738-R-95-025, 1995. Reregistration Eligibility Decision (RED) Sodium Fluoroacetate.